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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,378	11/23/2004	Georg Lutter	ROS-101	6218

23290 7590 11/17/2006

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/510,378	LUTTER, GEORG	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 September 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings were received on September 14 2006. Figures 2 and 3 are acceptable. Figure 5 is not acceptable for the reasons given below.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a sluice mechanism sealing at least one passage fluid-tight without the provision of an auxiliary catheter when the dilation unit disposed on the proximal side is in an inflated state and the coronary artery perfusion catheters with cuffs must be shown or the feature(s) canceled from the claim(s). It should be noted that the coronary cuffs as indicated in the amendment to Figure 5 appear to be on single lines. It is not clearly what these single lines represent as coronary perfusion catheters are tubular and thus should not be depicted by single lines. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because Figure 5 does not clearly show the components of the perfusion catheter arrangement, i.e., the catheters and dilation units are not clearly drawn. In lines 3-5 of page 14 of the response filed September 14 2006, Applicant indicated that the sluice element (11) and the dilation element (11') are separated from the perfusion catheter (1). However, the coronary perfusion catheter labeled "C" in Figure 5 is not shown clearly as it is unclear if there are two separate coronary perfusion catheters (C) being shown or one perfusion catheter (C). If there are two coronary perfusion catheters being shown, it is unclear if they are shown as a single line or a double line. It is also not clear what the line between the dilation element (11') and the perfusion catheter (1) is. This line is not labeled. If this line represents the sluice element (11), it would appear that the dilation element (11') is inside the sluice element (11). The arrows for sluice element (11) and coronary perfusion catheter(s) (C) do not seem to be clearly pointing to the corresponding components. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an

amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not mention a sluice mechanism sealing at least one passage fluid-tight without the provision of an auxiliary catheter when the dilation unit disposed on the proximal side is in an inflated state. Also, the specification does not mention at least one passage being designed in the manner of a rotatable ring seal which is surrounded by the perfusion catheter and by the dilation unit disposed on the proximal side. In the paragraph beginning "Through a..." on page 15, it is disclosed that the passage is disposed in a rotatable manner about the perfusion catheter with the aid of a rotatable ring seal placed about the perfusion catheter.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 5, it is not clear whether the at least one passage or the rotatable ring seal is being claimed as being surrounded by the perfusion catheter and the dilation unit disposed on the proximal side.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 7, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by St. Goar et al (U.S. Patent No. 6,090,096). In Figures 8, 9, and 10, St. Goar et al disclose a perfusion catheter (80) having at least one perfusion channel (98) designed as a hollow channel and dilation units (84 and 110). At least the dilation unit (110) which is disposed on the proximal side is provided with at least one passage (86) outside of the perfusion channel (98) and a sluice mechanism seals the passage (86) fluid-tight without the provision of an auxiliary catheter when the dilation unit (110) is in an inflated state. As to claim 2, in lines 19-34 of column 11, St. Goar et al teach that the

dilation units are disposed at a distance of at least 1 cm form each other. As to claim 3, the passage (86) is provided at a circumferential edge of the dilation unit, i.e., the edge of the dilation unit through which the passage projects and part of the passage is bound sickle-like by the circumferential edge of the dilation unit and the remaining part of the passage is bound by the aortic wall. As to claim 7, openings (102 and 100) are provide and, in lines 19-23 of column 8 and lines 50-54 of column 11, St. Goar et al teach providing a pump or pressurized fluid source (59). As to claim 9, a working channel (92) is provided with an opening (96). As to claim 10, the passage (86) is surrounded by an elastic channel, i.e., the dilation unit (110). As to claim 11, the dilation elements are connected to a supply line through which a fluid source is introduced for inflating.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al in view of Valley et al (U.S. Patent No. 5,814,016). St. Goar et al disclose the invention substantially as claimed. However, St. Goar et al do not disclose the passage being designed in the manner of a rotatable ring seal and the proximal dilation unit being disposed in a rotary manner about the perfusion catheter. In Figure 29, Valley et al show a catheter having proximal and distal dilation units and, in lines 10-55

of column 26, teach that the dilation unit can be rotated about the catheter to collapse the dilation unit to its lowest possible deflated profile when the catheter is introduced or withdrawn through a peripheral arterial access site. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of St. Goar et al to allow the dilation unit and, thus the passage, to be rotated about the catheter as taught by Valley et al as both St. Goar et al and Valley et al teach using the catheters within the arteries of a patient's heart and it is desirable to have the dilation unit in the lowest possible deflated profile when the catheter is being advanced through the narrow passageways of a patient's body.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al in view of Kong (Publication No. U.S. 2002/0120234). St. Goar et al disclose the invention substantially as claimed. However, St. Goar et al are silent on the dilation units being designed as suction elements and having a bell-shaped form with a suction line. In Figure 1, Kong shows a catheter where the dilation unit or balloon is designed as a suction element and has a bell-shaped form and teaches using a suction line to allow the balloon to maintain a fluid-tight seal to a wall of a blood vessel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dilation units of St. Goar et al to be a suction element with a bell-shaped form and a suction line as taught by Kong as both St. Goar et al and Kong teach that it is desirable for the dilation units to maintain a fluid-tight seal at the location in a patient's body where a surgical procedure is being performed.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al and Kong as applied to claim 12 above, and further in view of Wang et al (U.S. Patent No. 5,195,969). St. Goar et al and Kong disclose the invention substantially as claimed. St. Goar et al disclose the dilation units as being made of an elastic material and enclosing an inflatable volume. However, both St. Goar et al and Kong are silent on the dilation units being double-walled. Wang et al disclose a catheter having a double-walled dilation unit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the elastic dilation unit of St. Goar et al double-walled as taught by Wang et al as Wang et al teach that a double-walled dilation unit provides strength to the dilation unit so that it can be inflated safely and this is highly desirable when inflating dilation units in locations in a patient's body where a surgical procedure is being performed.

13. Claims 8, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al in view of Boyd et al (U.S. Patent No. 5,738,652). St. Goar et al discloses introducing coronary artery catheters (69 and 71) into the coronary arteries and inflating a cuff (75) which allows a blood flow to be ensured through the catheters into the coronary arteries. Furthermore, in lines 16-19 of column 8, St. Goar et al teach that other components and features of cardiopulmonary bypass systems may be used that would be apparent to those of skill in the art. St. Goar et al teach positioning the perfusion catheter inside the aorta so that the aortic valve is surrounded by the dilation units and inflating the dilation units so that the units are located close to the aortic wall in a fluid-tight manner. St. Goar et al also teach visualizing the aorta. St. Goar et al

disclose the invention substantially as claimed. However, St. Goar et al do not teach emptying the blood volume between the two dilation units by means of an auxiliary catheter projecting through the proximal dilation unit, severing the aortic valve by means of a separation instrument projecting through the proximal dilation unit, and conducting the severing under optical observation by means of an optic catheter where multiple passages or catheters are provided projecting through a dilation unit. In line 54 of column 12 to line 32 of column 13, Boyd et al teach using a cardiopulmonary bypass system and a catheter where a working volume is created between a dilation unit (11) and the aortic valve by removing the fluid within that area by introducing multiple catheters which project through the dilation unit. Boyd et al also teach using a cutter to sever the aortic valve and using an angioscope to observe the severing of the aortic valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter of St. Goar et al with multiple auxiliary catheters as taught by Boyd et al as Boyd et al teach that it is well known to use auxiliary catheters projecting through a dilation unit for creating a working volume, for severing the aortic valve, and for conducting the severing under optical observation.

Response to Arguments

14. Applicant's arguments filed September 14 2006 have been fully considered but they are not persuasive. St Goar et al disclose the dilation unit (110) with a passage (86) which is outside of the perfusion channel (98) as seen in Figure 9. At least one auxiliary catheter is considered to be able to be introduced into the passage (86) and/or

the perfusion channel (98). At least a portion of the passage (86) is considered to be completely surrounded by the dilation unit (110).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

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SUPERVISORY PATENT EXAMINER